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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/766,227 |
| | Filing Date | January 28, 2004 |
| | First Named Inventor | Richard C. Theuer |
| | Art Unit | Unknown |
| | Examiner Name | Unknown |
| Total Number of Pages in This Submission | Attorney Docket Number | 9850-000007/US |

| ENCLOSURES (check all that apply) | | | | |
|---|--|---|---------|--|
| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): References (17) Form 1449 (2 pages) Return Postcard | | |
| <table border="1"><tr><td>Remarks</td><td>The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed.</td></tr></table> | | | Remarks | The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed. |
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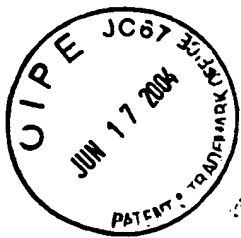
| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|--|----------------------------------|---------------|-------------------|
| Firm or Individual name | Harness, Dickey & Pierce, P.L.C. | Attorney Name | Donald R. Holland |
| | | Reg. No. | 35,197 |
| Signature | | | |
| Date | June 17, 2004 | | |

| CERTIFICATE OF TRANSMISSION/MAILING | | | |
|---|-------------------|------------------------|-----------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. | | | |
| Typed or printed name | Donald R. Holland | Express Mail Label No. | EV 404052980 US |
| Signature | | Date | June 17, 2004 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EV 404052980 US



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/766,227
Filing Date: January 28, 2004
Applicant: Richard C. Theuer
Group Art Unit: Unknown
Examiner: Unknown
Title: METHOD AND COMPOSITIONS FOR TREATING
GASTRIC HYPERACIDITY WHILE DIMINISHING THE
LIKELIHOOD OF PRODUCING VITAMIN DEFICIENCY
Attorney Docket: 9850-000007/US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. COPIES

A. ____ Submitted herewith is a legible copy of (i) each U.S. patent application publication and U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; (iii) for each cross-referenced pending U.S. application listed below in Section IV, the application specification including the claims, and any drawing of the application which caused it to be listed including the claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B. ____ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by

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or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. X Because the present application was/is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form 1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form 1449 are enclosed herewith.

D. ____ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search Report are listed on the attached Form-1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search Report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g))

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. X Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ____ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ____ See the attached foreign patent office communication from a counterpart foreign application.
2. ____ English translations are provided.
3. ____ Other:

C. ____ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ____ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Art Unit

V. THIS IDS IS BEING FILED UNDER

A. X 37 C.F.R. § 1.97(b): (check only one box)

1. ____ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.
2. ____ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.
3. X before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
4. ____ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ____ 37 C.F.R. § 1.97(c): (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ____ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).
2. ____ See the certification below. No fee is required.

C. ____ 37 C.F.R. § 1.97(d):

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ____ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. ____ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F. R. 1.704(d) below in section VII, if applicable; or

B. ____ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ____ Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 CFR 1.704(d)

The undersigned hereby states that:

____ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

A. ____ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. ____ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary

skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

Dated:

6/17/04

By:

Donald R. Holland

Donald R. Holland, Reg. No. 35,197
HARNES, DICKEY & PIERCE, P.L.C.
7700 Bonhomme, Suite 400
St. Louis, Missouri 63105
(314) 726-7500



FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 1 of 2

ATTORNEY DOCKET No.

9850-000007/US

SERIAL No.

10/766,227

APPLICANT

Richard C. Theuer

FILING DATE

January 28, 2004

GROUP

Unknown

U.S. PATENT DOCUMENTS

| Ref. Desig. | Examiner's Initials | Document Number | Date | Name | Class/ Subclass | (If appropriate) Filing Date |
|-------------|---------------------|-----------------|------------|-------------------|-----------------|------------------------------|
| 1. | | 5,817,338 | 10/06/1998 | Bergstrand et al. | | |
| 2. | | 6,132,771 | 10/17/2000 | Dupui et al. | | |
| 3. | | 6,174,548 | 01/16/2001 | Chen et al. | | |
| 4. | | 6,369,087 | 04/09/2002 | Whittle et al. | | |
| 5. | | 6,428,810 | 08/06/2002 | Bergstrand et al. | | |

FOREIGN PATENT DOCUMENTS

| Ref. Desig. | Examiner's Initials | Document Number | Date | Country | Class/ Subclass | Translation Yes | No |
|-------------|---------------------|-----------------|------|---------|-----------------|-----------------|----|
| | | | | | | | |

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

| Ref. Desig. | Examiner's Initials | |
|-------------|---------------------|---|
| 6. | | Haematological Adverse Effects of Histamine H ₂ -Receptor Antagonists, <i>Medical Toxicolog, Adverse Drug Experience Review</i> , 3(6): 430-448, (1988) |
| 7. | | CARMEL, R., Malabsorption of Food Cobalamin, <i>Baillière's Clinical Haematology</i> , Vol. 8, No. 3, 639-655 (1995) |
| 8. | | Dietary Reference Intakes, <i>FOOD AND NUTRITION BOARD, INSTITUTE OF MEDICINE</i> , pp. 146-147 |
| 9. | | MOWAT, C., et al., Alterations in Intragastric Nitrite and Vitamin C Levels During Acid Inhibitory Therapy, <i>BEST PRACTICE & RESEARCH CLINICAL GASTROENTEROLOGY</i> , Vol. 15, No. 3, pp 523-537 (2001) |
| 10. | | PORTER, S. C., et al., Coating of Pharmaceutical Dosage Forms, <i>Remington: The Science and Practice of Pharmacy, Twentieth Edition</i> , A. R. Gennaro et al., Editors, Lippincott-Williams & Wilkins, Chapter 46, pp. 894-902 (2000) |

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EV 404052980 US

FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Sheet 2 of 2

ATTORNEY DOCKET NO.

9850-000007/US

SERIAL NO.

10/766,227

APPLICANT

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GROUP

Unknown

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

| Ref. Desig. | Examiner's Initials | |
|-------------|---------------------|--|
| 11. | | RUSCIN, J. M., et al., Vitamin B ₁₂ Deficiency Associated with Histamine ₂ -Receptor Antagonists and a Proton-Pump Inhibitor, <i>The Annals of Pharmacotherapy</i> , Vol. 36, pp. 812-816 (2002) |
| 12. | | SCHENK, B. E., et al., Effect of Short- and Long-Term Treatment with Omeprazole on the Absorption and Serum Levels of Cobalamin, <i>Aliment Pharmacol Ther. Blackwell Science Ltd.</i> 10: 541-545 (1996) |
| 13. | | Ascorbic Acid, <i>The Merck Index</i> , 12 th Edition, pp.139-140 (1996) |
| 14. | | Calcium Ascorbate, <i>The Merck Index</i> , 12 th Edition, pp. 270-271 (1996) |
| 15. | | Cimetidine, <i>The Merck Index</i> , 12 th Edition, p. 383 (1996) |
| 16. | | Dehydroascorbic Acid, <i>The Merck Index</i> , 12 th Edition, p. 485 (1996) |
| 17. | | Famotidine, <i>The Merck Index</i> , 12 th Edition, p. 667 (1996) |
| 18. | | Lansoprazole, <i>The Merck Index</i> , 12 th Edition, p. 916 (1996) |
| 19. | | Omeprazole, <i>The Merck Index</i> , 12 th Edition, p. 1174 (1996) |
| 20. | | Rabeprazole, <i>The Merck Index</i> , 12 th Edition, p. 1392 (1996) |
| 21. | | Ranitidine, <i>The Merck Index</i> , 12 th Edition, p. 1395 (1996) |
| 22. | | Sodium Bicarbonate, <i>The Merck Index</i> , 12 th Edition, pp. 1471-1472 (1996) |

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.